

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1458]

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Certifier D. Hawkins

Medical Devices: Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA." This document describes a means by which apnea monitors may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying apnea monitors into class II (special controls).

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance entitled "Class II Special Controls Document: Apnea Monitors; Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed labels to assist that office in processing your request, or fax your request to 301-443-8818.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: William Noe, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8609.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 22, 2000 (65 FR 57355), FDA announced the availability of this draft guidance document and invited interested persons to comment on it by December 21, 2000. FDA also announced in that notice its intention to modify the guidance so that it would apply to apnea monitors for patients of all ages. In that same issue of the **Federal Register** (65 FR 57301), FDA proposed to classify the apnea monitor into class II with this guidance document as the special control. This guidance supersedes the draft guidance entitled "Guidance for Infant/Child Apnea Monitor 510(k) Submissions."

FDA received comments on the draft guidance from one manufacturer. We considered this manufacturer's comments and included some of its suggestions in our revised guidance. We revised the guidance to make it applicable to devices intended for adults as well as infants and children, added information

concerning industry's option to submit an abbreviated 510(k) when relying on a class II special controls guidance document, and retitled the guidance to reflect these changes.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on "Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

In order to receive the guidance entitled "Class II Special Controls Guidance Document: Apnea Monitors; Guidance for Industry and FDA" via your fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1178) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved

applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in the labeling section of this guidance discussing labeling under 21 CFR 807.87(e) was approved under OMB control number 0910–0120. The collection of information in the labeling section of this guidance discussing labeling under 21 CFR 801.109 was approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document

and received comments may be seen in the Dockets Management Branch
between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 7/5/02
July 5, 2002.

Linda S. Kahan

Linda S. Kahan,
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Center for Devices and Radiological Health.
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